Patent
241/120

To: Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL – UTILITY

Sir:

Transmitted herewith for filing is a **utility** patent application:

Inventor(s): Yue–Teh JANG, Ross S. Tsugita, Bruce S. Addis, Tracy D. Maahs, and Jean C. Chang

Title: ENDOLUMINAL OCCLUSION–IRRIGATION CATHETER WITH ASPIRATION CAPABILITIES AND METHODS OF USE

I. PAPERS ENCLOSED HEREWITH FOR FILING UNDER 37 CFR § 1.53(b):

13 Page(s) of Written Description

11 Page(s) Claims

1 Page(s) Abstract

10 Sheets of Drawings ☒ Informal ☐ Formal

II. ADDITIONAL PAPERS ENCLOSED IN CONNECTION WITH THIS FILING:

☒ Declaration

☒ Power of Attorney ☒ Separate ☐ Combined with Declaration

☒ Assignment to EMBOL–X, Inc. and assignment cover sheet

☒ Verified Statement establishing **"Small Entity"** under 37 CFR §§ 1.9 and 1.27

☐ Priority Document No(s):

☒ Information Disclosure Statement w/PTO 1449 ☒ Copy of Citations

☒ Preliminary Amendment

☒ Return Postcard

CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' (Label No. EL508736143US) in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

December 22, 1999
Date of Deposit

Cynthia B Pacheco
Cynthia B Pacheco

III. THE FILING FEE HAS BEEN CALCULATED AS SHOWN BELOW:

BASIC FILING FEE:							$760.00
Total Claims	24	–	20	= 4	x	$18.00	$72.00
Independent Claims	6	–	3	= 3	x	$78.00	$234.00
Multiple Dependent Claims	$260	(if applicable)				☐	$0.00
TOTAL OF ABOVE CALCULATIONS							$1,066.00
Reduction by ½ for Filing by Small Entity. Note 37 CFR §§ 1.9, 1.27, 1.28. If applicable, Verified Statement must be attached.						☒	$533.00
Misc. Filing Fees (Recordation of Assignment — $40)							$0.00
TOTAL FEES DUE HEREWITH							$533.00

IV. METHOD OF PAYMENT OF FEES

☒ Charge Lyon & Lyon's Deposit Account No. **12–2475** in the amount of $533.00. A duplicate copy of this document is attached.

☐ This application is being filed without fee or Declaration under 37 CFR § 1.53.

V. AUTHORIZATION TO CHARGE FEES

The Commissioner is authorized to credit any overpayment and to charge any underpayment to Lyon & Lyon's Deposit Account No. **12–2475** for the following:

☒ 37 CFR § 1.16 – **(Filing fees and excess claims fees)**

☒ 37 CFR § 1.17 – **(Any application processing fees)**

☒ 37 CFR § 1.21 – **(Assignment recording fees)**

VI. CORRESPONDENCE ADDRESS

Please send all correspondence to Customer Number 22249:

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Please direct all inquiries to John Kappos, at (949) 567–2300.

Respectfully submitted,

LYON & LYON LLP

Dated: December 22, 1999

By: John Kappos
John Kappos, Reg. No. 37,861
Attorneys for Applicant

Attorney's Docket No. 241/120

Applicant or Patentee: Yue-Teh Jang, Ross Tsugita, Bruce Addis, Tracy Maahs, and Jean C. Chang
Serial or Patent No.: Not yet assigned
Filed or Issued: Submitted herewith
For: ENDOLUMINAL OCCLUSION-IRRIGATION catheter WITH ASPIRATION CAPABILITIES AND METHODS OF USE

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

__ the owner of the small business concern identified below:

_x_ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN EMBOL–X, INC.

ADDRESS OF CONCERN 645 CLYDE AVENUE, MOUNTAIN VIEW, CALIFORNIA 94043–2213

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed, to and remain with the small business concern identified above with regard to the invention, entitled

ENDOLUMINAL OCCLUSION-IRRIGATION catheter WITH ASPIRATION CAPABILITIES AND METHODS OF USE

by inventor(s) Yue-Teh Jang, Ross S. Tsugita, Bruce S. Addis, Tracy D. Maahs, and Jean C. Chang

described in

_X_ the specification filed herewith
__ the application serial no. _____, filed _____.
__ patent no. _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING YUE-TEH JANG
TITLE OF PERSON SIGNING President and Chief Executive Officer
ADDRESS OF PERSON SIGNING 645 Clyde Avenue, Mountain View, California 94043-2213

SIGNATURE _____ DATE 12/7/98

Patent
241/120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Tsugita et al.

Serial No.: Not yet assigned

Filed: Submitted herewith

For: ENDOLUMINAL OCCLUSION–IRRIGATION CATHETER WITH ASPIRATION CAPABILITIES AND METHODS OF USE

Group Art Unit: Not yet assigned

PRELIMINARY AMENDMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Before the calculation of claim fees, please amend the above–identified application as follows.

IN THE CLAIMS

Please cancel claims 22–29, 31–35, and 37–41, without prejudice.

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Cynthia B. Pacheco
Cynthia B. Pacheco

REMARKS

Applicant requests entry of the above amendment before examination, and before calculation of claim fees for the above-identified application.

Respectfully submitted,

LYON & LYON LLP

Dated: December 22, 1999

By: John Kappos

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S P E C I F I C A T I O N

ENDOLUMINAL OCCLUSION-IRRIGATION CATHETER WITH ASPIRATION CAPABILITIES AND METHODS OF USE

Field of the Invention

The present invention generally relates to medical devices for protecting a patient from distal embolization during interventional procedures, such as angioplasty or stent placement for treatment of vascular stenosis. More particularly, the devices comprise a catheter having irrigation and aspiration capabilities, and a guidewire carrying a distal expandable occluder. An endovascular instrument, such as an angioplasty catheter, is insertable into a lumen of the aspiration catheter.

Background of the Invention

Treatments of vascular stenosis or lesions during endovascular procedures, such as atherectomy, balloon angioplasty with or without stent placement, or ablation therapy, are associated with increased risk of distal embolization. Tissue debris, calcium, atheromatous plaque, and/or thrombi generated during the procedure often become lodged downstream in a small vessel of vital organs, causing tissue ischemia or infarction. For example, transient ischemic attack (TIA) and cerebral infarction (stroke) are common complications of performing endovascular procedures on the ascending aorta and the carotid artery.

To reduce the risk of distal embolism, several devices are employed for use in

endovascular procedures. For example, blood filters can be deployed distal to a vascular lesion to capture emboli. However, disadvantages associated with the blood filters are that (1) dislodgment of embolic material can occur during insertion and retrieval of the filter device, and (2) blood filters cannot easily be used in small vessels, (*e.g.*, a saphenous vein graft measuring 3 or 4 mm).

Another catheter system described in U.S. Pat No. 5,833,650 includes occlusion members for providing proximal and distal occlusion to a vascular lesion. Each occlusion member communicates with an inflation lumen. The catheter includes irrigation and aspiration lumens for removing embolic debris generated during the procedure. The catheter also includes a device introducing lumen, which further increases the overall size and diameter of the catheter, making the catheter impracticable for use in smaller vessels.

Theron developed a device having an insertion catheter, a dilation catheter, and an occlusion catheter assembled in a coaxial arrangement, U.S. Pat No. 5,423,742. The catheter device is inserted across a vascular lesion which is dilated by the dilation catheter. Emboli generated during the dilation is removed by suction through the insertion catheter, while the occlusion catheter provides vascular occlusion distal to the vascular lesion. The major disadvantage associated with the device is that some of the embolic material will not be removed by irrigation and suction, thereby leaving the patient at risk for embolic complication.

Thus, there is a need for devices and methods which effectively remove embolic material generated during endovascular procedures, and that can be used in vessels having various diameters.

Summary of the Invention

The present invention provides an endoluminal catheter system adapted for insertion into arteries of various sizes, including the femoral artery, the iliac artery, the popliteal artery, the renal artery, the inferior mesenteric artery, the superior mesenteric artery, the celiac artery, the coronary artery, the common carotid artery, the internal carotid artery, the external carotid artery, the subclavian artery, the axillary artery, and the brachial artery. The catheter system is also adapted for insertion into a patient's venous vasculature, including the femoral vein, the iliac vein, the superficial femoral vein, the deep femoral vein, the renal vein, the coronary artery, the internal jugular vein, the external jugular vein, the subclavian vein, the saphenous vein, the azygous vein, the superior vena cava, and the inferior vena cava. The catheter system can accommodate a variety of endovascular instruments, including a blood filter, an angioplasty catheter, a valveoplasty catheter, an electrode catheter, internal vessel segregating or isolating dams, an endoscopic camera, a pressure monitor, a stent, a graft, a shunt, a perfusion catheter, and endoscopic devices.

In a first embodiment, the catheter system includes a guidewire, an endovascular catheter, *e.g.*, angioplasty catheter, and an aspiration catheter. The guidewire has a proximal end, and an expandable occluder mounted on a distal end. The aspiration catheter has first and second lumens. The first lumen communicates between a proximal end and a distal end, and is adapted to receive the guidewire and the endovascular catheter. The second lumen communicates with at least one distal fluid infusion port. In certain embodiments, the catheter includes an aspiration lumen communicating with one or a plurality of distal aspiration ports.

In another embodiment, 2, 3, 4, 5, 6, or any other number of infusion ports are disposed radially about the distal end of the aspiration catheter. The infusion ports are shaped to direct fluid in a circular path radially and distally beyond the distal end of the aspiration catheter. In certain embodiments, the infusion ports are directed radially outward and angled relative to the radius of the catheter.

In another embodiment, the expandable occluder is mounted on a distal end of a support wire, which includes an infusion lumen and port(s). The support wire is insertable through the lumen of the endovascular catheter which includes distal aspiration port(s) and lumen.

In a first method of treating an endovascular lesion using the catheter system described above, the guidewire, which has the expandable occluder placed in a collapsed state, is inserted in the lumen of the aspiration catheter. The aspiration catheter carrying the guidewire is then inserted into a vessel, and the guidewire is advanced to position the occluder distal to a region of interest. An endovascular device, *e.g.*, an angioplasty catheter, is inserted over the proximal end of the guidewire, and advanced to position a dilatation member within the region of interest. The aspiration catheter is advanced over the guidewire and positioned proximal the dilatation member. The occluder on the guidewire is expanded to occlude the vascular lumen distal to the lesion. The dilatation member is expanded to treat the vascular lesion and collapsed after luminal patency is achieved. Fluid, such as saline or Ringer's lactate solution, is infused through the infusion lumen and ports to irrigate the treated lumen. Fluid, blood, and embolic debris are removed through the aspiration lumen under suction. The occluder on the guidewire remains expanded during irrigation and aspiration. In certain embodiments, infusion and

aspiration of fluid can create a venturi effect in the vascular lumen between the expanded occluder and the aspiration catheter to facilitate removal of loose emboli and embolic material partially attached to the vascular wall. The surgeon can tell that removal of embolic material is complete after the aspirated fluid turns from red to clear and is free of any debris. In this way, the catheter system is capable of complete removal of emboli.

In another method, fluid is infused through the lumen of a support wire to irrigate the region of interest. Embolic debris, blood, and fluid are removed through the distal aspiration ports and lumen of the endovascular catheter. Radiopaque contrast agent is infused through the infusion lumen to assess luminal patency under fluoroscopy. After treatment of the vascular lesion, the occluder is collapsed, and the catheter system is removed from the vessel.

It will be understood that there are several advantages in using the catheter systems and methods disclosed herein for treating a vascular lesion. For example, the devices (1) can be inserted in arteries or veins of various diameter, (2) provide near-total capture of embolic material, thereby dramatically reducing the risk of distal embolization, (3) accommodate a variety of endovascular instruments, and (4) provide treatment of vascular lesions and emboli protection utilizing one catheter system, thereby obviating the need for device exchange.

Brief Description of the Drawings

Fig. 1 depicts an embodiment of the catheter system for treating a vascular lesion according to the present invention.

Fig. 2 depicts a guidewire inserted in a vessel.

Fig. 3 depicts an aspiration catheter inserted over the guidewire of Fig. 2.

Fig. 4A depicts the catheter system of Fig. 1 inserted in a vessel for treatment of atheromatous lesions.

Fig. 4B depicts a cross-sectional view of the catheter system of Fig. 4A through sectional line B – B.

Fig. 4C depicts a cross-sectional view of the catheter system of Fig. 4A through sectional line C – C.

Fig. 5A depicts irrigation and aspiration of vascular debris after angioplasty using the catheter system of Fig. 1.

Fig. 5B depicts the catheter system of Fig. 5A having the angioplasty catheter withdrawn within the lumen of the aspiration catheter.

Fig. 6A depicts another embodiment of the aspiration catheter having a plurality of infusion ports shaped to direct fluid flow.

Fig. 6B depicts a distal view of the catheter system of Fig. 6A from cross-sectional line B – B.

Fig. 7 depicts cross-sectional views of another embodiment of the aspiration catheter irrigating vascular lumens of varying diameters.

Fig. 8 depicts another embodiment of the catheter system having a stent deployment catheter.

Fig. 9A depicts the catheter system of Fig. 8 deploying a stent into a vessel.

Fig. 9B depicts the stent deployment catheter of Fig. 9A withdrawn into the lumen of the aspiration catheter.

Fig. 10 depicts the catheter system of Fig. 8 inserted into the left common

carotid artery for treatment of carotid stenosis.

Fig. 11 depicts another embodiment of the catheter system having a support wire inserted through an endovascular catheter.

Fig. 12A depicts an embodiment of the support wire having an expandable occluder mounted on a distal end.

Fig. 12B depicts the occluder of the support wire of Fig. 12A in a collapsed state.

Fig. 12C depicts a cross-sectional view of the support wire of Fig. 12A through section line B – B.

Fig. 12D depicts a cross-sectional view of the support wire of Fig. 12B through section line D– D.

Detailed Description

Referring now to the drawings, an embodiment of the catheter system for treating a vascular lesion is depicted in Fig. 1. The system generally comprises guidewire 10, angioplasty catheter 20, and aspiration catheter 30. Guidewire 10 has proximal end 11 and distal end 12. An expandable occluder, shown as balloon 15 which communicates with inflation lumen 16 and proximal port 17, is mounted on distal end 12. Balloon 15 can be expanded by infusing air, gas, or saline through proximal port 17. Guidewire 10 is inserted through lumen 22 of angioplasty catheter 20. Lumen 22 communicates with proximal end 21 and distal end 23. Dilatation member, shown as expandable balloon 25 which communicates with inflation lumen 26 and inflation port 27, is mounted on distal end 23 of the catheter. Dilatation balloon 25 can be expanded by infusing air, gas, or

saline through proximal port 27. Angioplasty catheter 20 is inserted through lumen 33 of aspiration catheter 30. Lumen 33 communicates with proximal end 31 and distal end 32. Hemostatic valve 40 is included in proximal end 31 to prevent back flow of blood during catheter insertion. The aspiration catheter includes infusion ports 35 at distal end 32. Each infusion port communicates with infusion lumen 36 and proximal infusion port 37. In certain embodiments, the infusion ports communicate with a single infusion lumen and port. Lumen 33, which communicates with aspiration lumen 39, is adapted for aspiration of fluid, air or debris. Lumen 39 extends from proximal end 31 and is adapted for attachment to a vacuum at a proximal end.

In use, guidewire 10 with balloon occluder 15 in a collapsed state is inserted through an incision on a peripheral artery and advanced to vascular lesion 101 as depicted in Fig. 2. Aspiration catheter 30 is then inserted over guidewire 10 into vessel 100 proximal to lesion 101 as depicted in Fig. 3. Alternatively, guidewire 10 is inserted into lumen 33 of aspiration catheter 30 prior to insertion into the vessel.

Angioplasty catheter 20 is inserted into lumen 33 of aspiration catheter 30 and advanced to position dilatation balloon 25 over lesion 101 as depicted in Fig. 4A. Distal end 32 of the aspiration catheter is positioned proximal of balloon 25. Balloon 15 of the guidewire is then inflated to occlude the lumen of vessel 100, thereby protecting emboli from traveling downstream to other organs when dilatation balloon 25 is expanded against lesion 101. In other methods, balloon 15 is inflated before the positioning of angioplasty catheter 20 in the region of interest, and in other methods before positioning the aspiration catheter 30 proximal to the region of interest. A cross-sectional view of the catheter system proximal to lesion 101 is depicted in Fig. 4B. A cross-sectional view of

the catheter system acting to cause dilation of lesion 101 is depicted in Fig. 4C.

During angioplasty, inflation of the dilatation balloon often causes fissure of an atheromatous lesion, which commonly includes calcium, cholesterol plaque, and thrombi, thereby liberating embolic debris. After the dilatation balloon is expanded against the atheromatous lesion to re-establish lumenal patency, the dilatation balloon is deflated. Radiopaque contrast agent can be infused through infusion ports 35 to assess the diameter of the vascular lumen under fluoroscopy. Fluid, such as saline or Ringer's lactate solution, is infused through infusion lumens 36 and ports 35 to irrigate the vascular region including the distal end of the angioplasty catheter as shown in Fig. 5A. Lumen 33 is attached to suction, and fluid, blood, and debris are aspirated into lumen 33 and removed. The distal end of the angioplasty catheter is maintained proximal to balloon occluder 15 and distal to aspiration catheter during irrigation and aspiration of embolic debris.

Alternatively, the distal end of angioplasty catheter 20 is withdrawn proximal, into lumen 33 of aspiration catheter 30, in certain cases, prior to irrigation and aspiration as shown in Fig. 5B. The color of the aspirate is monitored at the proximal end of aspiration catheter. Removal of embolic debris is complete when the color of the aspirate turns from red to clear and the aspirate is free of any debris. After angioplasty, balloon 15 on the guidewire is deflated to re-establish vascular flow, and the catheter system is removed from the vessel.

Fig. 6A depicts another embodiment of aspiration catheter 30 having a plurality of infusion ports 35 which comprise angled slots. Ports 35 are shaped to direct fluid radially and distally beyond distal end 32. When suction is attached to the lumen of

aspiration catheter 30, a venturi effect is created, causing the irrigated fluid to circulate circumferentially about catheter 30, similar to a whirlwind as depicted in Fig. 6B. This irrigation/aspiration system increases the contact of fluid with the vascular wall, thereby increasing the effectiveness of removing embolic debris and loosely attached plaque or thrombi.

Fig. 7 depicts cross-sectional views of another embodiment of aspiration catheter 30 having angled infusion ports 35 for directing fluid flow. Catheter 30 is inserted in vessels of varying diameter. The catheter is also effective in generating a whirlpool-like irrigation pattern when the catheter is positioned adjacent the vascular wall. The catheter can be repositioned within around the vascular lumen to remove embolic debris.

Fig. 8 depicts another embodiment of the catheter system having stent deployment catheter 50 inserted through lumen 33 of aspiration catheter 30. Stent 55 is mounted on distal end 53 of catheter 50 and is operable through actuating mechanism 57 at the proximal end. In certain embodiments, stent 55 is made from shape-memory material, *e.g.*, nitinol. The stent is therefore self-expanding at body temperature and is simply released to actuate. Lumen 54 of catheter 20 is adapted to receive guidewire 10, which has an arcuate distal end 12 to assist guidance through vessels. The aspiration catheter includes infusion ports 35 at distal end 32. Each infusion port communicates with infusion lumen 36 and proximal infusion port 37. Aspiration catheter 30 also includes aspiration lumens 38, which communicate with suction lumens 39 adapted for attachment to a vacuum at a proximal end. In certain embodiments, aspiration lumens 38 communicate with a single suction lumen 39.

In use, aspiration catheter 30 and guidewire 10 with balloon occluder 15 in a collapsed state are inserted into a vessel. The guidewire is advanced distal to vascular lesion 101 as depicted in Fig. 9A. Distal end 32 of the aspiration catheter is positioned proximal lesion 101. Stent deployment catheter 50 with stent 55 in a collapsed state is inserted into lumen 33 of aspiration catheter 30 and advanced within lesion 101. Balloon 15 of the guidewire is inflated, either before or after introduction of the aspiration catheter and stent deployment catheter, to occlude the lumen of vessel 100, thereby protecting emboli from traveling downstream to other organs when stent 55 is expanded against lesion 101 by operating the actuating mechanism. After lumenal patency is re-established by deployment of the stent, fluid is infused through lumen infusion lumens 36 and ports 35 to irrigate the vascular lumen within stent 55 while the distal end of catheter 50 remains within the stent as shown in Fig. 9A. Lumens 38 are attached to suction, and fluid, blood, and debris are aspirated into lumen 38 and removed.

Alternatively, the distal end of catheter 50 is withdrawn into lumen 33 of aspiration catheter 30 prior to irrigation and aspiration as shown in Fig. 9B. Removal of embolic debris is complete when the color of the aspirate turns from red to clear and the aspirate is free of any debris. After stent placement, balloon 15 on the guidewire is deflated to re-establish vascular flow, and the catheter system is removed from the vessel.

Fig. 10 depicts the catheter system of Fig. 8 inserted into left common carotid artery 150 for treatment of carotid stenosis. The catheter system is inserted through an incision in left femoral artery 160 and advanced into the left common carotid artery via descending aorta 155. Stent 55 is deployed within lesion 101 while balloon occluder 15 of guidewire 10 is expanded to prevent distal embolization to the brain. Embolic material

generated during carotid stenting is removed by irrigation and aspiration through catheter 30, thereby reducing the risk of cerebral ischemia and/or infarct.

Fig. 11 depicts another embodiment of the catheter system for treatment of a vascular lesion. Expandable balloon occluder 15 is mounted on distal end 71 of support wire 70, which is insertable through the lumen of angioplasty catheter 20.

In use, prior to inserting support wire 70 into a vessel, balloon occluder 15 is placed in a collapsed state by closing inflation valve 19 as depicted in Figs. 12B and 12D. An endoluminal device, such as angioplasty catheter 20 having angioplasty balloon 25 mounted on a distal end, is inserted over support wire 70, and within aspiration catheter 30. After distal end 71 of the support wire is positioned downstream the region of interest, balloon occluder 15 is expanded by opening inflation valve 19 and infusing fluid or air through inflation lumen 16 as depicted in Figs. 12A and 12C. Fluid, such as saline or Ringer's lactate, is infused through lumen 77 and port 75 to irrigate within the region of interest. Embolic debris, blood, fluid, and air are aspirated either or both of through aspiration port 76 of angioplasty catheter 76 and aspiration port 32 of aspiration catheter 30.

The length of the aspiration catheter will generally be between approximately 40 and 120 centimeters, preferably between approximately 60 and 80 centimeters. The length of the guidewire will generally be between approximately 50 and 130 centimeters, preferably between approximately 70 to 100 centimeters. The inner diameter of the aspiration catheter will generally be between approximately 0.5 and 2.0 centimeters, preferably approximately 0.8 and 1.5 centimeters for use in the aorta. The inner diameter of the guidewire will generally be between approximately 0.005 and 0.02 inches,

preferably approximately 0.008 and 0.014 inches. The diameter of the expanded occluder on the guidewire will generally be between 2 and 6 centimeters, preferably approximately 3 and 5 centimeters for use in the aorta. For use in the carotid arteries, the inner diameter of the aspiration catheter will generally be between approximately 0.2 and 1.5 centimeters, preferably approximately 0.5 and 1.0 centimeters, and the diameter of the expanded occluder on the guidewire will generally be between 1 and 3 centimeters, preferably approximately 1.5 and 2.5 centimeters. The foregoing ranges are set forth solely for the purpose of illustrating typical device dimensions. The actual dimensions of a device constructed according to the principles of the present invention may obviously vary outside of the listed ranges without departing from those basic principles.

Although the foregoing invention has, for purposes of clarity of understanding, been described in some detail by way of illustration and example, it will be obvious that certain changes and modifications may be practiced which will still fall within the scope of the appended claim. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, can be used in combination with the features of any other embodiment.

What is claimed is:

1. An endoluminal aspiration catheter, comprising:

a guidewire having a proximal end, a distal end, and an expandable occlusive member mounted on the distal end;

an angioplasty catheter having a proximal end, a distal end, a lumen therebetween, and an expandable dilatation member mounted on the distal end, the lumen adapted to receive the guidewire; and

an aspiration catheter having a proximal end, a distal end, a first lumen therebetween adapted to receive the angioplasty catheter, and a second lumen extending and communicating with at least one distal fluid infusion port.

2. The catheter of claim 1, wherein the expandable occlusive member is a balloon, and wherein the guidewire further comprises an inflation lumen communicating with the balloon.

3. The catheter of claim 1, wherein the expandable dilatation member is a balloon, and wherein the angioplasty catheter further comprises an inflation lumen communicating with the balloon

4. The catheter of claim 1, wherein the aspiration catheter comprises a plurality of distal fluid infusion ports.

5. The catheter of claim 4, wherein the infusion ports are disposed radially about the distal end of the aspiration catheter.

6. The catheter of claim 1, wherein the aspiration catheter further comprises an aspiration lumen extending and communicating with at least one distal aspiration port.

7. The catheter of claim 4, wherein the infusion ports are shaped to direct fluid in a circular path radially and distally beyond the distal end of the aspiration catheter.

8. The catheter of claim 1, wherein the aspiration catheter is free of balloons.

9. The catheter of claim 4, wherein the infusion ports are directed radially outward and angled relative to the radius of the catheter.

10. The catheter of claim 1, wherein the proximal end of the aspiration catheter includes a hemostatic valve.

11. A method for treatment of a vascular lesion, comprising the steps of:

introducing a guidewire into a vessel, the guidewire having an expandable occlusive member mounted on a distal end;

advancing the guidewire to a region of interest and positioning the occlusive member downstream of the region of interest;

advancing an angioplasty catheter over the guidewire and positioning a dilatation member within the region of interest, the dilatation member being mounted on the distal end of the angioplasty catheter;

advancing an aspiration catheter over the guidewire and positioning the aspiration catheter proximal the dilatation member;

expanding the occlusive member;

expanding the dilatation member within the region of interest; and

aspirating fluid and embolic debris from the region of interest while the expanded dilatation member is maintained within the region of interest.

12. The method of claim 11, wherein the step of expanding the dilatation member further comprises the step of deploying a stent within the region of interest.

13. The method of claim 11, wherein the aspiration catheter is free of balloons.

14. The method of claim 11, wherein the expandable occlusive member is a balloon, and wherein the guidewire further comprises an inflation lumen communicating with the balloon.

15. The method of claim 11, wherein the expandable dilatation member is a balloon, and wherein the angioplasty catheter further comprises an inflation lumen communicating with the balloon.

16. The method of claim 11, wherein the step of aspirating fluid comprises the steps of:

infusing fluid into the region of interest through a lumen and infusion port of the guidewire; and

suctioning fluid from the region of interest.

17. The method of claim 16, wherein the fluid is suctioned from the region of interest through a separate lumen.

18. The method of claim 16, wherein the fluid is fluoroscopic contrast medium.

19. The method of claim 18, further comprising the step of visualizing the contrast medium under fluoroscopy.

20. The method of claim 11, further comprising the step of monitoring the color of the aspirated fluid to determine completion of the aspiration.

21. A method for treatment of a vascular lesion, comprising the steps of:

introducing a guidewire into a vessel, the guidewire having an expandable occlusive member mounted on a distal end;

advancing the guidewire to a region of interest and positioning the occlusive member downstream of the region of interest;

advancing a catheter with self-expanding stent over the guidewire and positioning the stent within the region of interest;

advancing an aspiration catheter over the guidewire and positioning the aspiration catheter proximal the stent;

expanding the occlusive member;

expanding the stent within the region of interest; and

aspirating fluid and embolic debris from the region of interest.

22. The method of claim 21, wherein the catheter further comprises a dilatation member mounted on the distal end of the catheter, and wherein the method further comprises the step of aspirating fluid and embolic debris from the region of interest while the expanded dilatation member is maintained within the region of interest.

23. The method of claim 21, wherein the expandable occlusive member is a balloon, and wherein the guidewire further comprises an inflation lumen communicating with the balloon.

24. The method of claim 21, wherein the step of aspirating fluid comprises the steps of:

infusing fluid into the region of interest through a lumen and infusion port of the aspiration catheter; and

suctioning fluid from the region of interest.

25. The method of claim 24, wherein the fluid is fluoroscopic contrast medium.

26. The method of claim 25, further comprising the step of visualizing the contrast medium under fluoroscopy.

27. The method of claim 21, further comprising the step of monitoring the color of the aspirated fluid to determine completion of the aspiration.

28. The method of claim 24, wherein the fluid is infused into the region of interest through infusion ports shaped to direct the fluid in a circular path radially and distally beyond the distal end of the aspiration catheter.

29. The method of claim 21, wherein the step of aspirating fluid comprises the step of infusing fluid into the region of interest through a lumen and infusion port of the guidewire.

30. An endoluminal aspiration catheter, comprising:

a guidewire having a proximal end, a distal end, an expandable occlusive member mounted on the distal end, and an irrigation port proximal the expandable occlusive member;

an angioplasty catheter having a proximal end, a distal end, a lumen therebetween, and an expandable dilatation member mounted on the distal end, the lumen adapted to receive the guidewire; and

an aspiration catheter having a proximal end, a distal end, a lumen therebetween adapted to receive the angioplasty catheter, and an aspiration port.

31. The catheter of claim 30, wherein the expandable occlusive member is a balloon, and wherein the guidewire further comprises an inflation lumen communicating with the balloon.

32. The catheter of claim 30, wherein the expandable dilatation member is a balloon, and wherein the angioplasty catheter further comprises an inflation lumen communicating with the balloon.

33. The catheter of claim 30, wherein the aspiration port communicates with the lumen of the aspiration catheter.

34. The catheter of claim 30, wherein the aspiration catheter is free of balloons.

35. The catheter of claim 30, wherein the proximal end of the aspiration catheter includes a hemostatic valve.

36. A method for treatment of a vascular lesion, comprising the steps of:

introducing a guidewire into a vessel, the guidewire having an expandable occlusive member mounted on a distal end and an irrigation port proximal the expandable occlusive member;

advancing the guidewire to a region of interest and positioning the occlusive member downstream of the region of interest;

advancing a therapeutic catheter over the guidewire and positioning the catheter within the region of interest;

advancing an aspiration catheter over the guidewire and positioning the aspiration catheter proximal the therapeutic catheter;

expanding the occlusive member;

performing an endoluminal procedure within the region of interest;

infusing fluid through the irrigation port; and

aspirating fluid and embolic debris through the aspiration catheter.

37. The method of claim 36, wherein the therapeutic catheter is an angioplasty catheter having a proximal end, a distal end, a lumen therebetween, and an expandable dilatation member mounted on the distal end, the lumen adapted to receive the guidewire.

38. The method of claim 36, wherein the therapeutic catheter is an atherectomy catheter having a proximal end, a distal end, a lumen therebetween, and an atherectomy assembly mounted on the distal end, the lumen adapted to receive the guidewire.

39. The method of claim 36, wherein the therapeutic catheter is a stent deployment catheter having a proximal end, a distal end, a lumen therebetween, and an expandable stent mounted on the distal end, the lumen adapted to receive the guidewire.

40. The method of claim 39, wherein the stent deployment catheter includes a self-expanding stent.

41. The method of claim 39, wherein the stent deployment catheter includes a dilatation balloon.

42. A method for treatment of a vascular lesion, comprising the steps of:

introducing a guidewire into a vessel, the guidewire having an expandable occlusive member mounted on a distal end;

advancing the guidewire to a region of interest and positioning the occlusive member downstream of the region of interest;

advancing an aspiration catheter over the guidewire and positioning the aspiration catheter proximal the dilatation member, the aspiration catheter having a first lumen communicating with a first distal port and a second lumen communicating with a second distal port;

expanding the occlusive member; and

infusing fluid through the first lumen and first distal port and aspirating fluid and embolic debris through the second lumen and second distal port while the occlusive member is expanded.

ABSTRACT

A catheter system comprising a guidewire, an endovascular catheter, and an aspiration catheter. The guidewire has an expandable occluder mounted on a distal end. The guidewire and the endovascular catheter are insertable into a lumen of the aspiration catheter. The aspiration catheter also includes infusion and aspiration lumen(s) and port(s). Methods of using the catheter system for treating a vascular lesion and removing embolic material during the procedure are also disclosed.

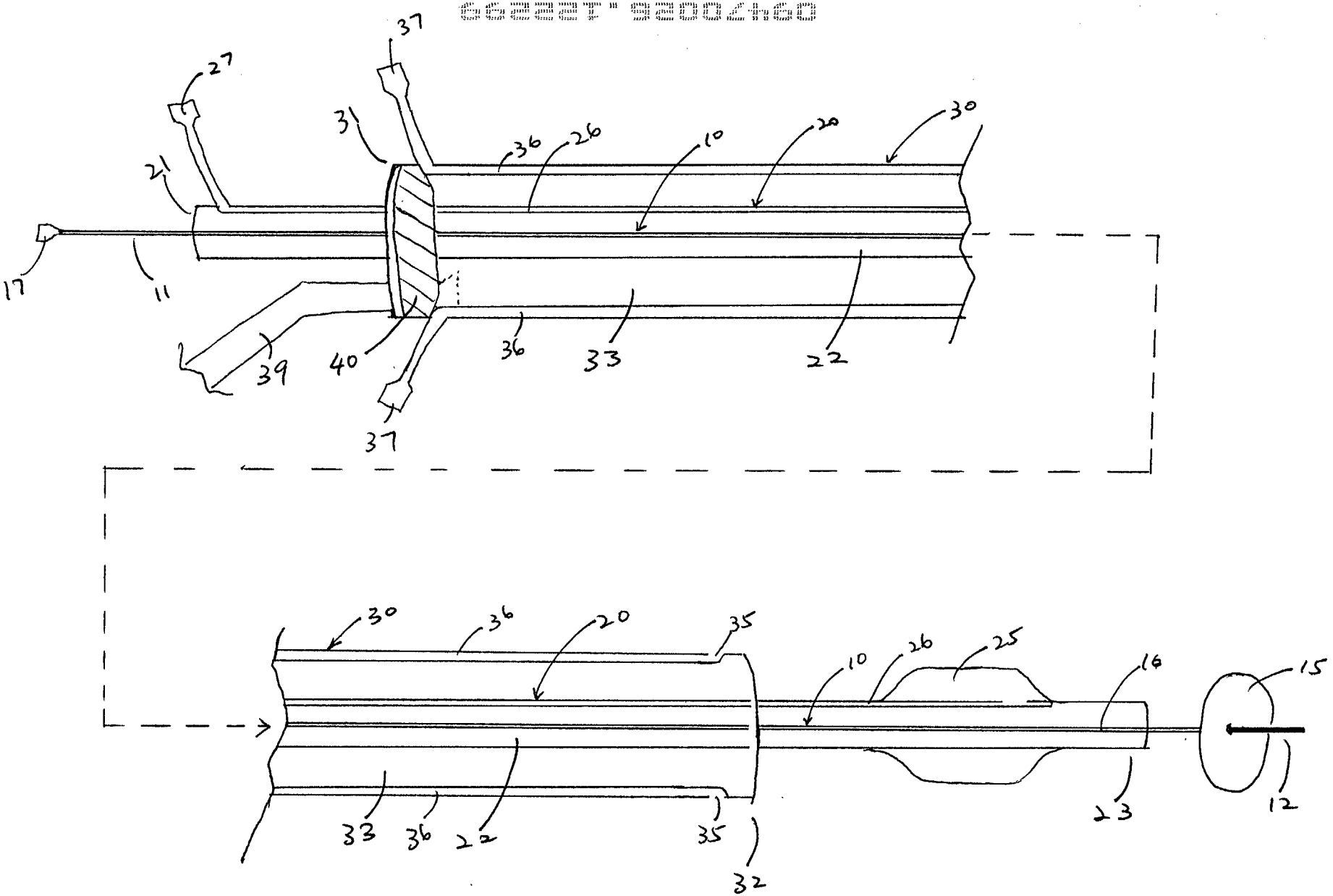
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FIG. 1

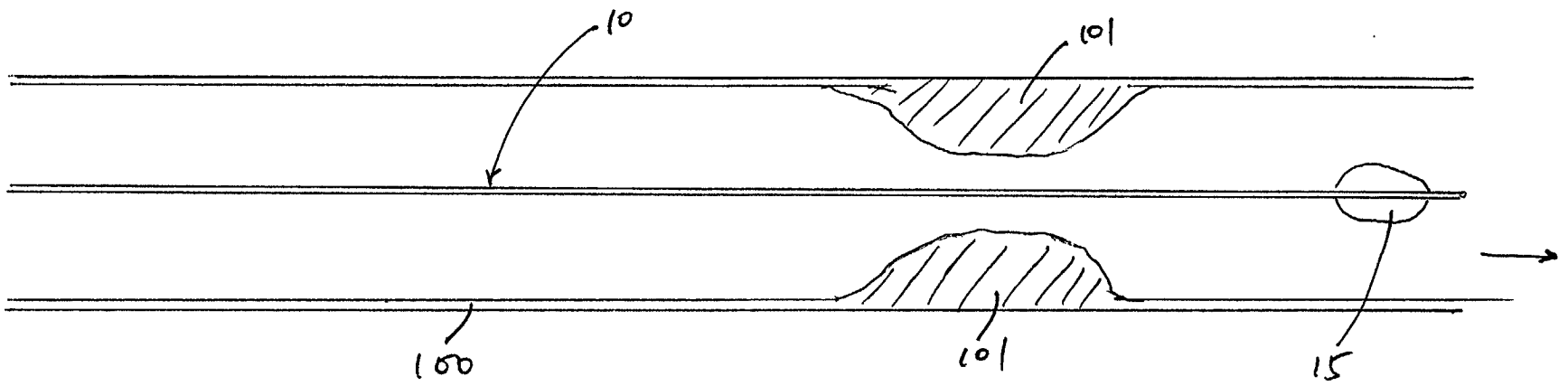

FIG. 2

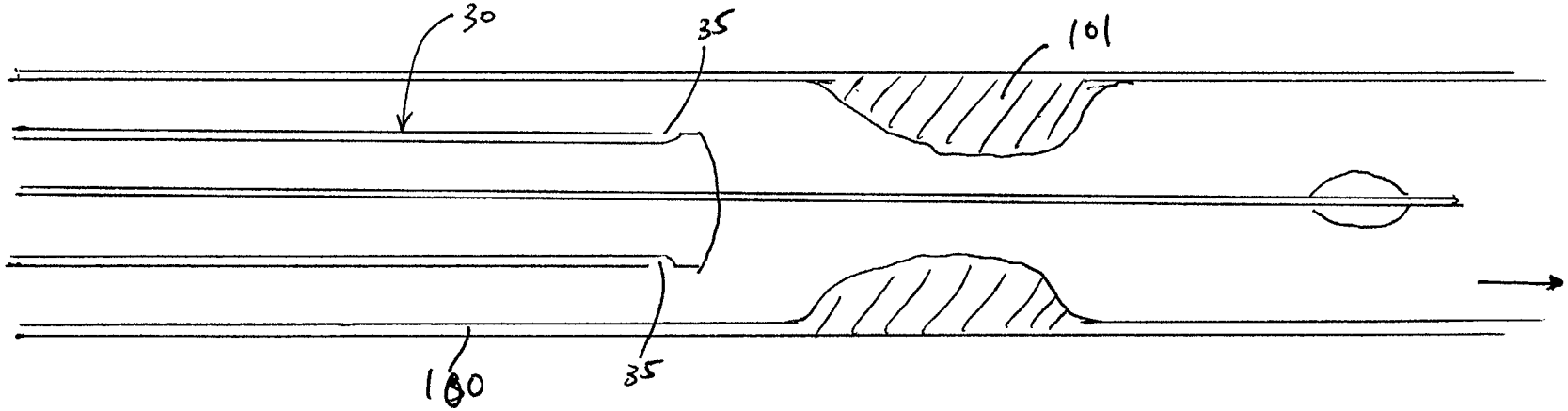

FIG. 3

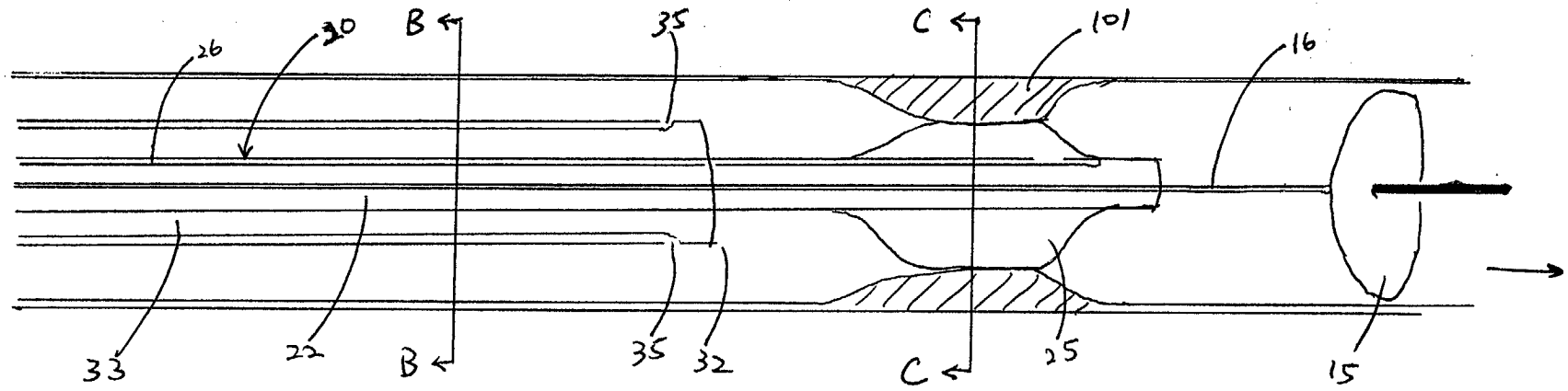

FIG. 4A

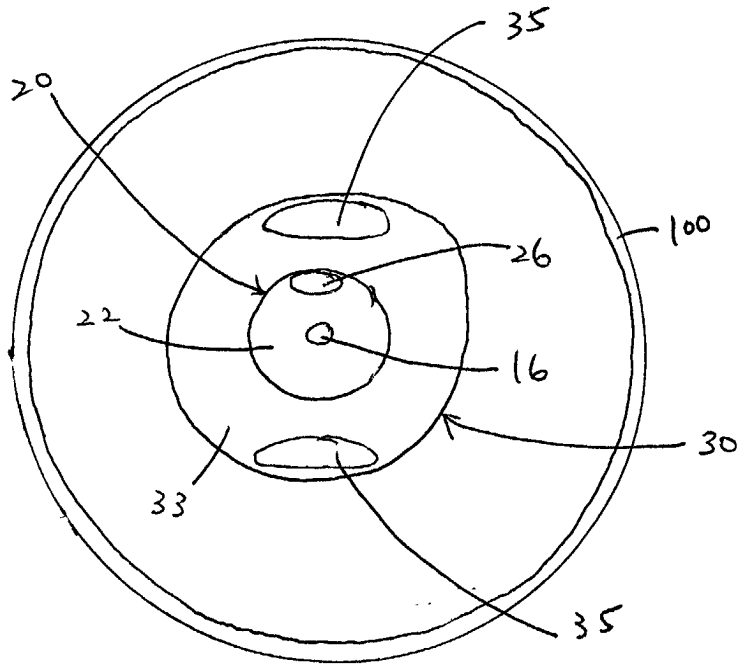

FIG. 4B

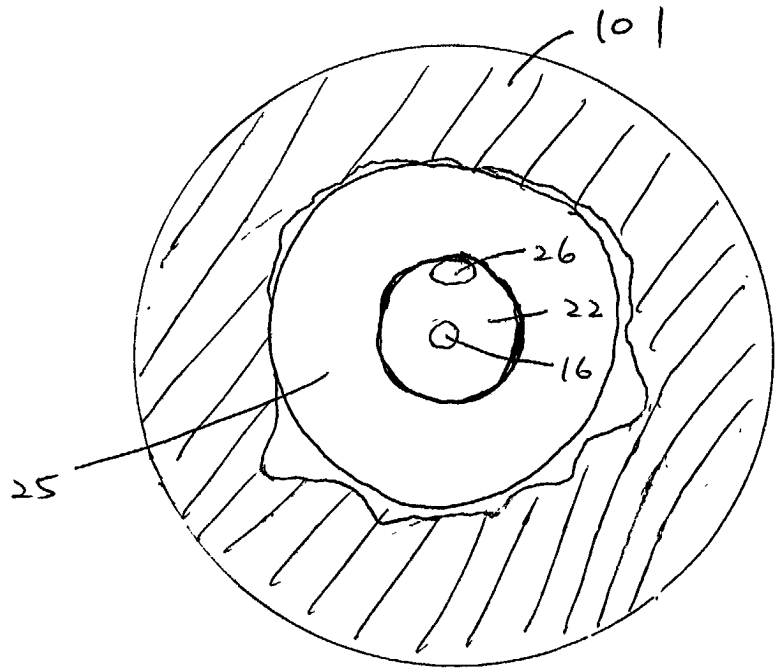

FIG. 4C

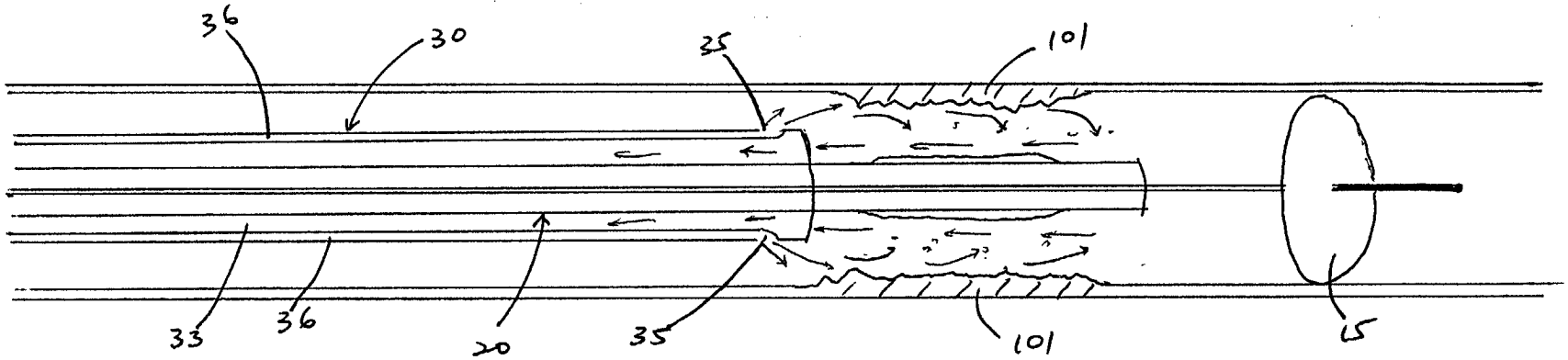

FIG. 5A

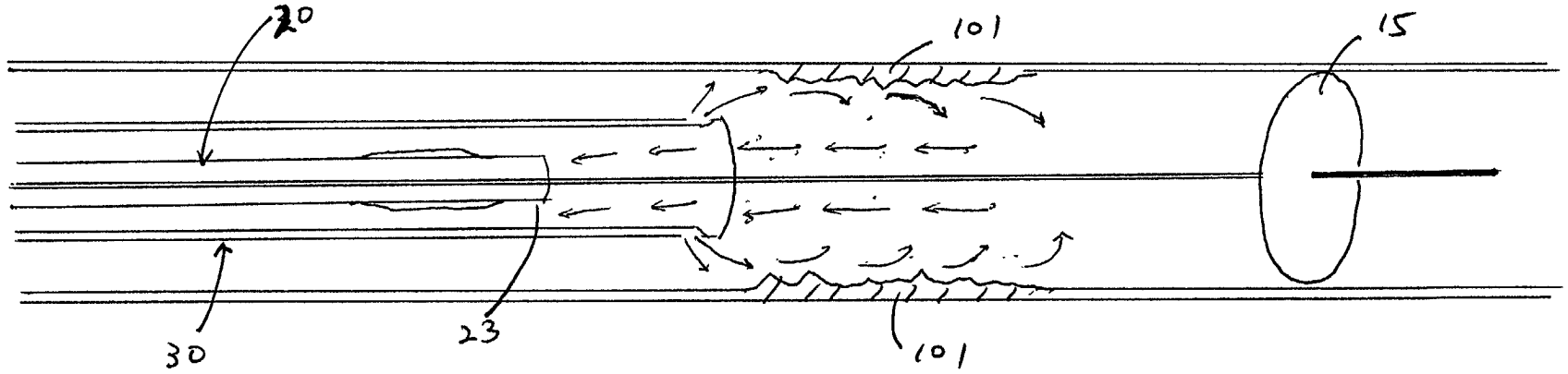

FIG. 5B

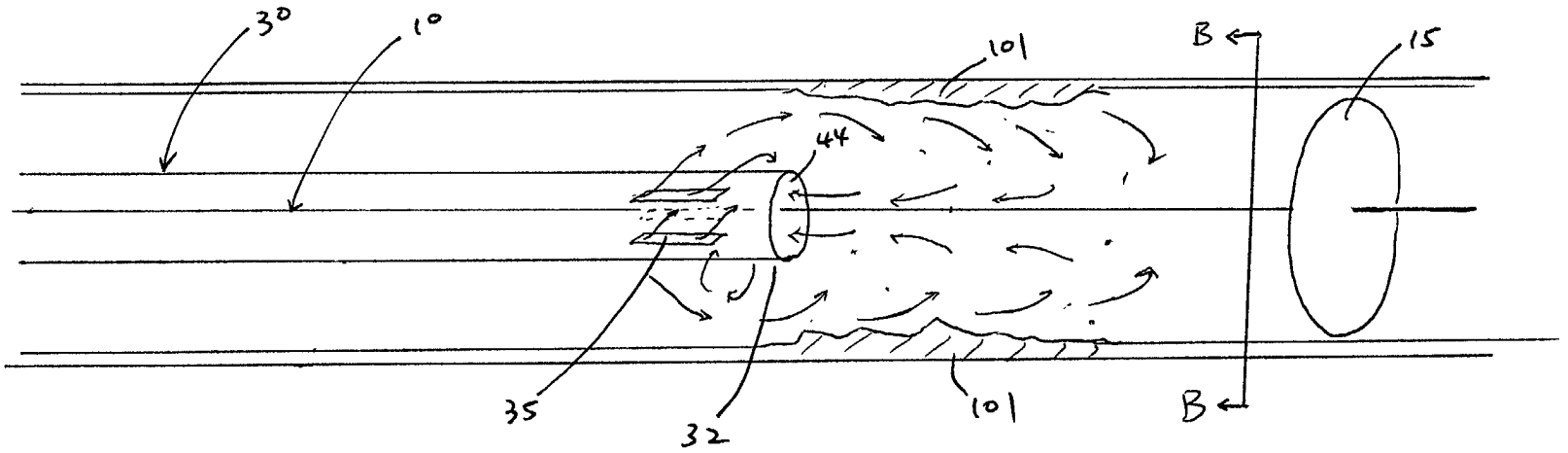

FIG. 6A

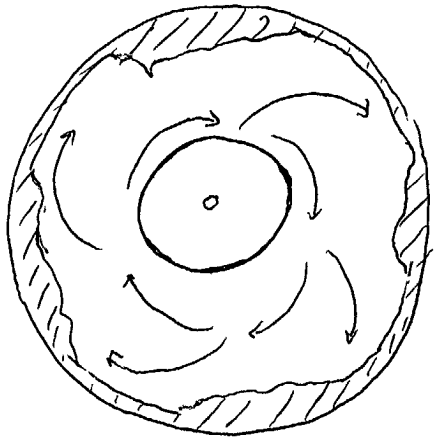

FIG. 6B

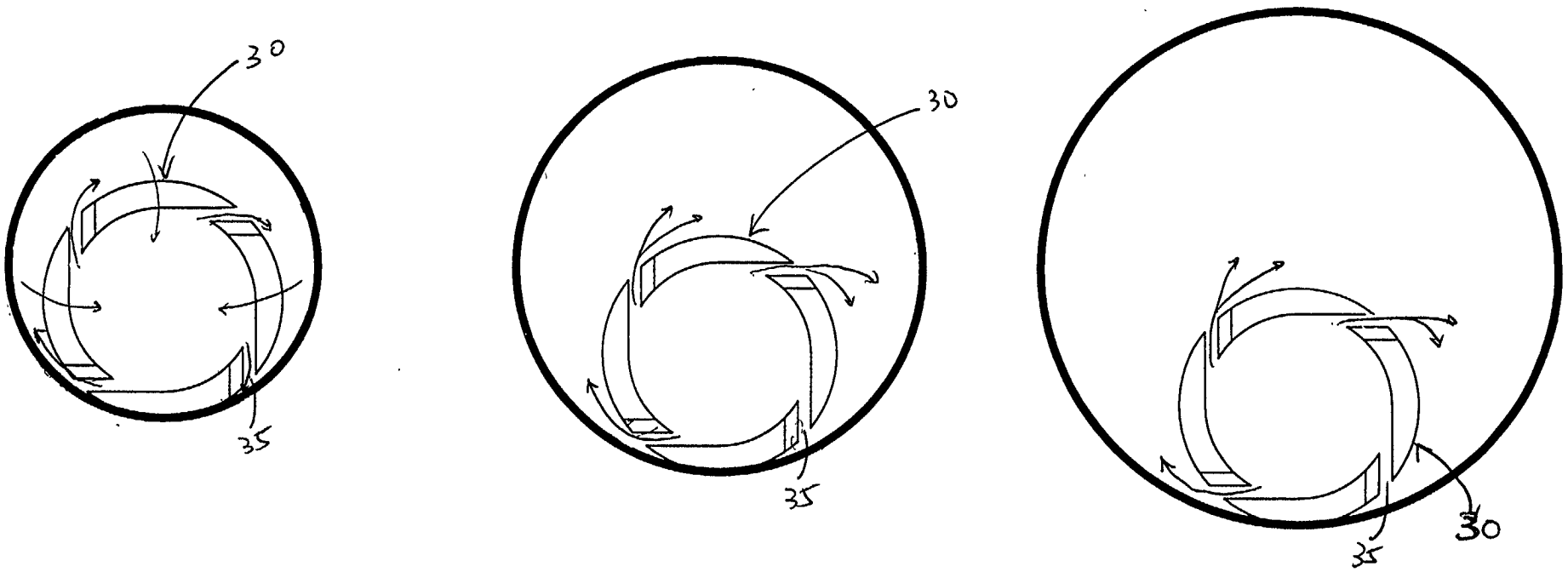

FIG. 7

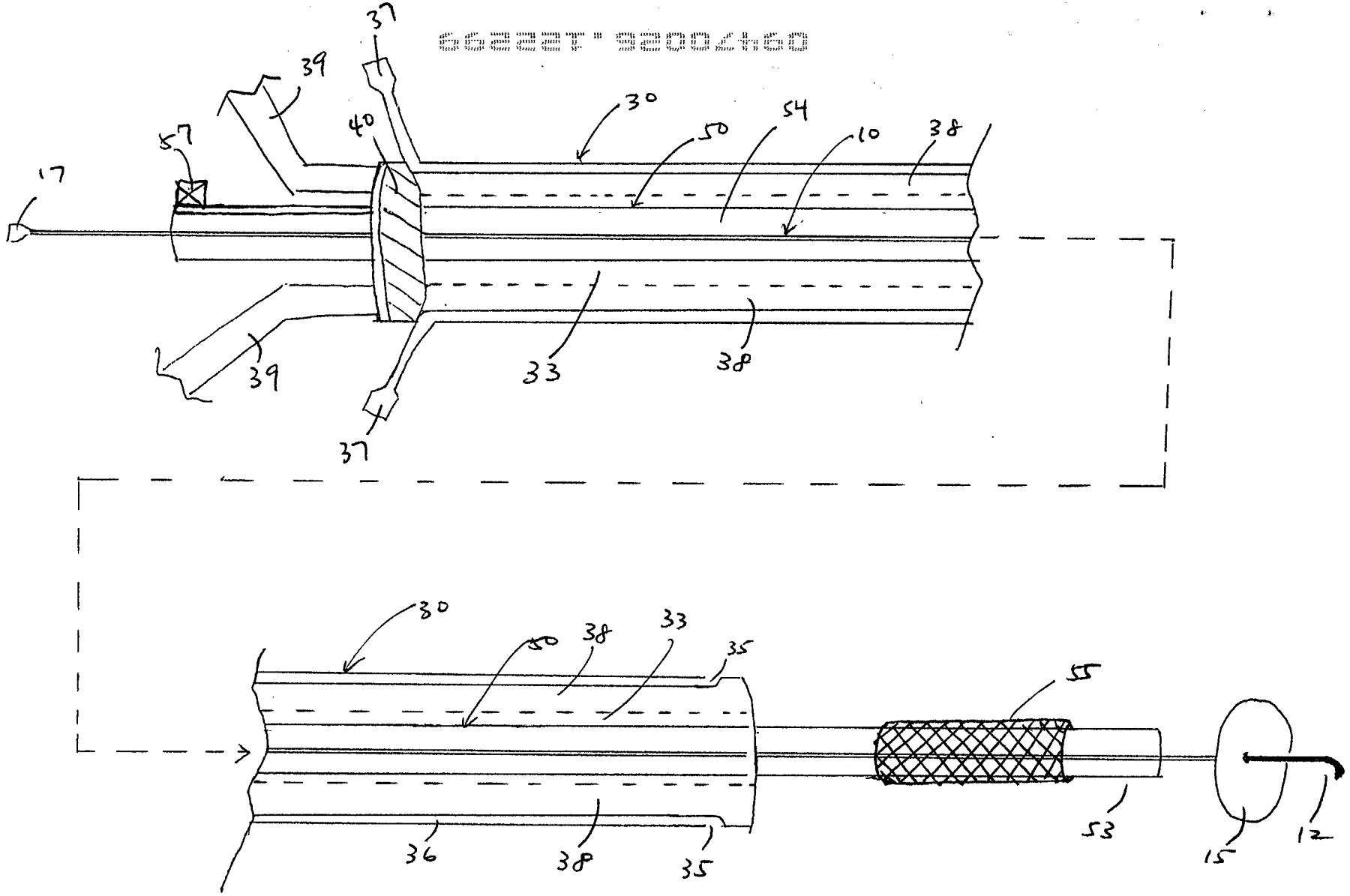
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FIG. 8

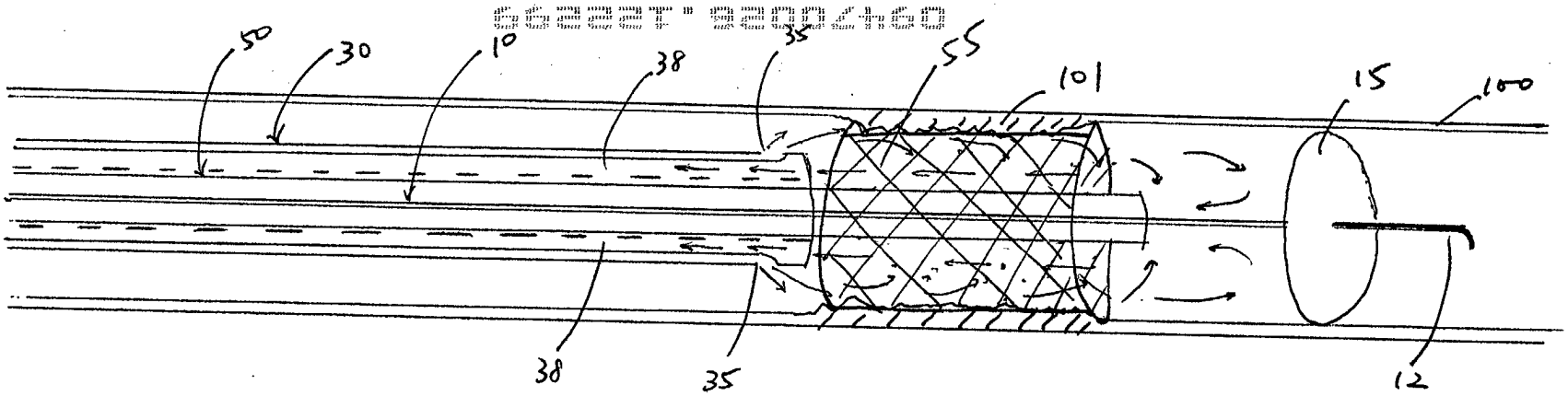
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FIG. 9A

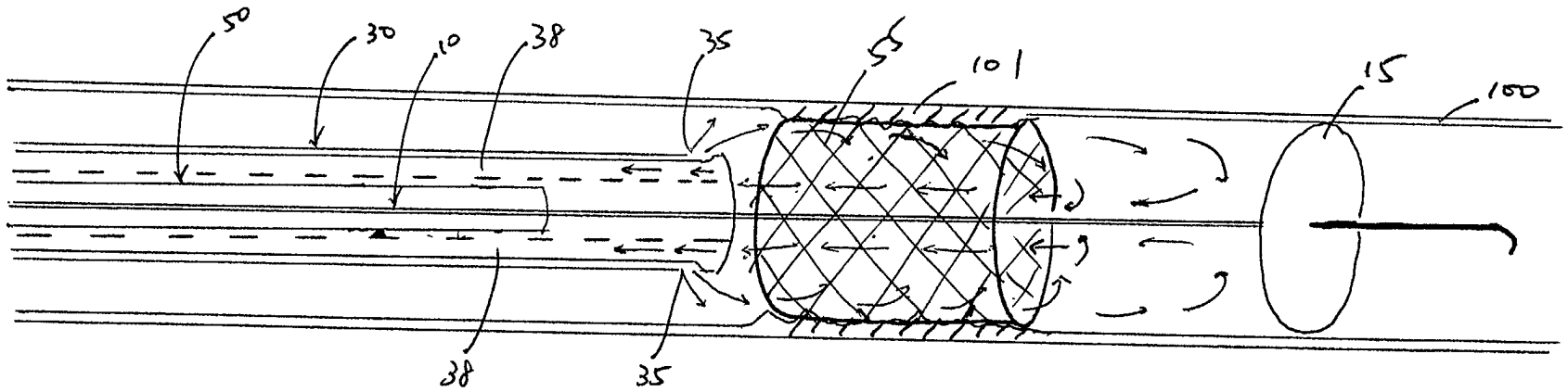
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FIG. 9B

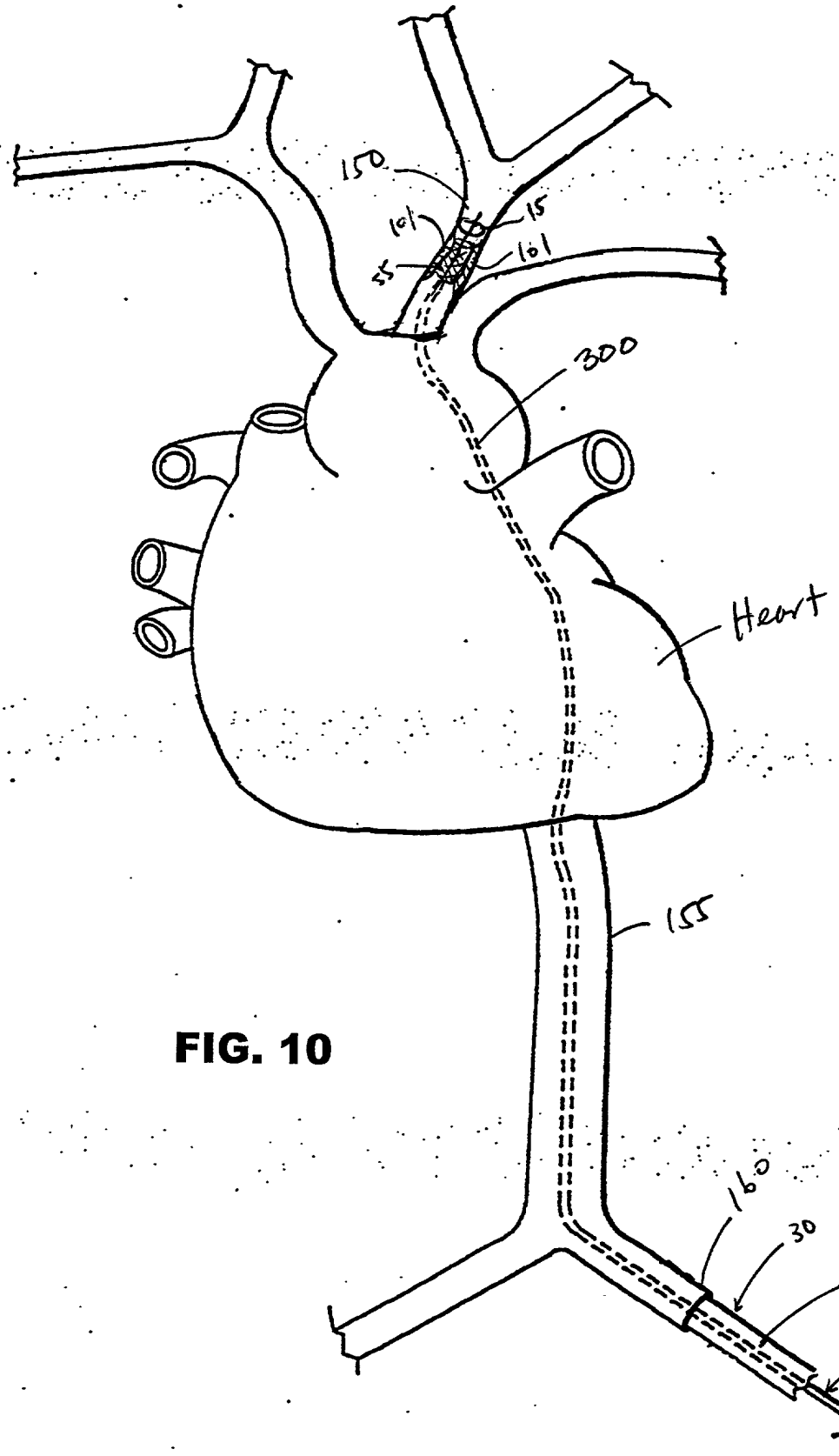

FIG. 10

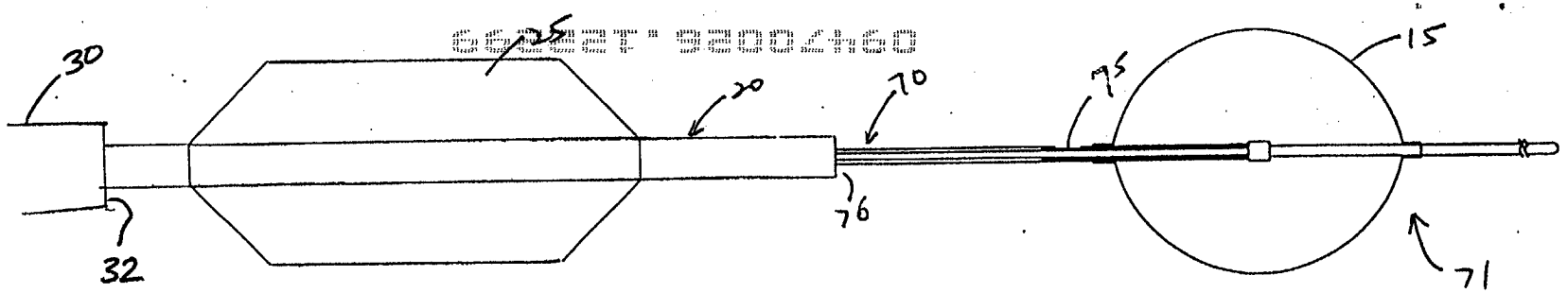

FIG. 11

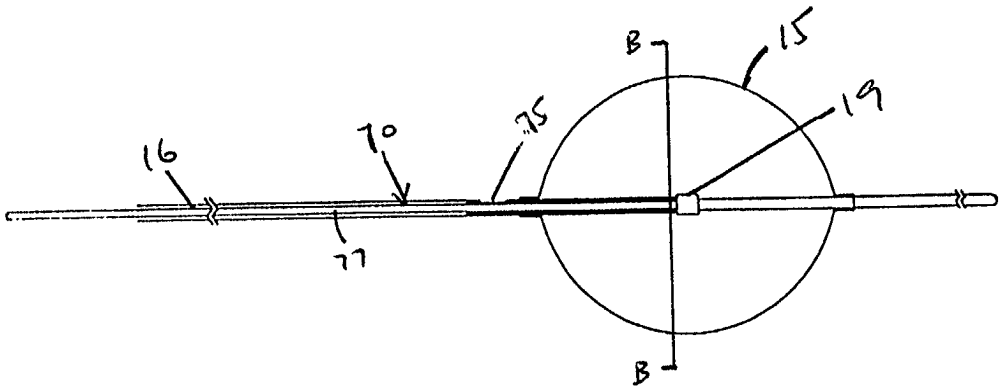

FIG. 12A

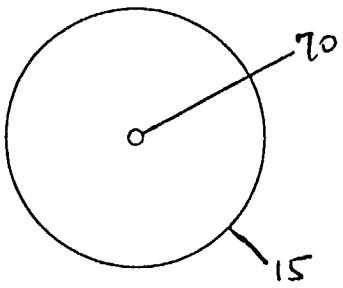

FIG. 12C

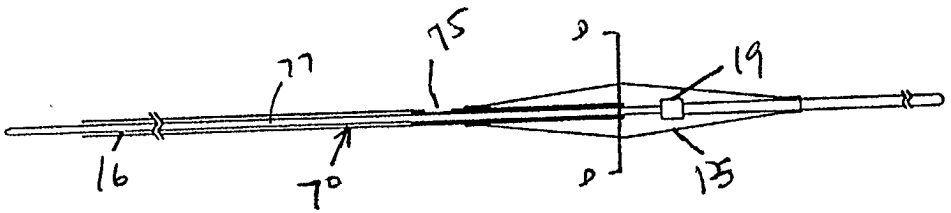

FIG. 12B

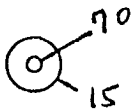

FIG. 12D

DECLARATION
Utility Application

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **ENDOLUMINAL OCCLUSION-IRRIGATION CATHETER WITH ASPIRATION CAPABILITIES AND METHODS OF USE** the specification of which

(Check One)
☒ is attached hereto OR
☐ was filed on _____ as United States Application Serial No. Not yet assigned or PCT International Application No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Date of Filing	Priority Claimed Yes	Priority Claimed No

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date	Status-Patented, Pending or Abandoned

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	POST OFFICE ADDRESS	1610 Nantucket Circle, #213	City Santa Clara	State or Country CA	Zip Code 95054
	FULL NAME OF INVENTOR	FIRST Name JEAN	MIDDLE Initial C.	LAST Name CHANG	
205	RESIDENCE & CITIZENSHIP	City Santa Clara	State or Foreign Country California	Country of Citizenship USA	
	POST OFFICE ADDRESS	320 Manzanita Avenue	City Santa Clara	State or Country CA	Zip Code 95051

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 201	Signature of Inventor 204
Date 12/7/99	Date 12.7.99
Signature of Inventor 202	Signature of Inventor 205
Date 12/7/99	Date 12.7.99
Signature of Inventor 203	
Date 12-7-99	

(Signatures should conform to names as presented at 201 et seq. above.)

POWER OF ATTORNEY
By Assignee

EMBOL–X, Inc., assignee(s) of the application for United States Letters Patent for an improvement in ENDOLUMINAL OCCLUSION-IRRIGATION CATHETER WITH ASPIRATION CAPABILITIES AND METHODS OF USE by Yue-Teh Jang, Ross S. Tsugita, Bruce S. Addis, Tracy D. Maahs, and Jean C. Chang the specification of which is

☒ filed herewith, or
☐ filed _____ having Serial No. _____.

hereby appoints as its attorneys and/or agents, with full power of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Roland N. Smoot, Reg. No. 18,718; Conrad R. Solum, Jr., Reg. No. 20,467; James W. Geriak, Reg. No. 20,233; Robert M. Taylor, Jr., Reg. No. 19,848; Samuel B. Stone, Reg. No. 19,297; Douglas E. Olson, Reg. No. 22,798; Robert E. Lyon, Reg. No. 24,171; Robert C. Weiss, Reg. No. 24,939; Richard E. Lyon, Jr., Reg. No. 26,300; John D. McConaghy, Reg. No. 26,773; William C. Steffin, Reg. No. 26,811; Coe A. Bloomberg, Reg. No. 26,605; J. Donald McCarthy, Reg. No. 25,119; John M. Benassi, Reg. No. 27,483; James H. Shalek, Reg. No. 29,749; Allan W. Jansen, Reg. No. 29,395; Robert W. Dickerson, Reg. No. 29,914; Roy L. Anderson, Reg. No. 30,240; David B. Murphy, Reg. No. 31,125; James C. Brooks, Reg. No. 29,898; Jeffrey M. Olson, Reg. No. 30,790; Steven D. Hemminger, Reg. No. 30,755; Jerrold B. Reilly, Reg. No. 32,293; Paul H. Meier, Reg. No. 32,274; John A. Rafter, Jr., Reg. No. 31,653; Kenneth H. Ohriner, Reg. No. 31,646; Mary S. Consalvi, Reg. No. 32,212; Lois M. Kwasigroch, Reg. No. 35,579; Lawrence R. LaPorte, Reg. No. 38,948; Robert C. Laurenson, Reg. No. 34,206; Carol A. Schneider, Reg. No. 34,923; Hope E. Melville, Reg. No. 34,874; Michael J. Wise, Reg. No. 34,047; Richard J. Warburg, Reg. No. 32,327; Kurt T. Mulville, Reg. No. 37,194; Theodore S. Maceiko, Reg. No. 35,593; Bruce G. Chapman, Reg. No. 33,846; and F. T. Alexandra Mahaney, Reg. No. 37,668; Stephen S. Korniczky, Reg. No. 34,853; James P. Brogan, Reg. No. 35,833; David A. Randall, Reg. No. 37,217; Christopher A. Vanderlaan, Reg. No. 37,747; and John Kappos, Reg. No. 37,861, and Jon Hallman, Reg. No. 42, 622.

Send Correspondence to: John Kappos	LYON & LYON LLP 633 W Fifth St., Suite 4700 Los Angeles, CA 90071-2066	Direct Telephone calls to: (714) 751–6606

I, the undersigned, declare that I have reviewed copies of the documentary evidence establishing chain of title to the patent application identified above from the inventor(s) to the assignee(s) which is filed for recordation herewith. To the best of the undersigned's knowledge and belief, title is in the assignee(s) identified above. Furthermore, the undersigned is empowered to sign this document on behalf of the assignee(s).

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Post Office Address 645 Clyde Avenue, Mountain View, CA 94043–2213	
Signature of Declarant or Assignee:	Date: 12/7/99

Full Name of Declarant If Other Than Assignee:	Yue–Teh Jang
Title of Declarant:	President and CEO
Address of Declarant:	645 Clyde Avenue, Mountain View, CA 94043–2213

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